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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,119	06/14/2001	Andrew D. Ellington	119927-1050	8203

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

22

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,119

Applicant(s)

ELLINGTON ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-136 is/are pending in the application.
- 4a) Of the above claim(s) 15-127 and 129-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14, 128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The specification as filed states "This application is a continuation-in-part of United States Serial No. 60/212097." This is improper since according to MPEP § 201.07 "[A]n application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "continuation" of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation-in-part of the provisional application."

Oath/Declaration

2. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, see the 3rd and 6th inventor's residence and P.O. box addresses.

Election/Restrictions

3. Claims 15-127 and 129-136 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 21.
4. Applicant's election without traverse of Group I, claims 1-14, and 128 in Paper No. 21 is acknowledged.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-13, and 128 are rejected under 35 USC 102(b) as being anticipated by Burke et al. (US Patent No. 5,663,064)

Claim 1, and those claims dependent thereon are drawn to a polynucleotide that is regulated by a polypeptide comprising a regulatable, catalytically active polynucleotide, wherein the peptide interacts with the polynucleotide to affect its catalytic activity. Claim 128 is drawn to a vector comprising: a regulatable, catalytically active polynucleotide, wherein the peptide molecule interacts with the polynucleotide to affect its catalytic activity. For prior art purposes, claims 12-13 are interpreted such that the term "the peptide" is considered to refer back to the limitation "the polypeptide" as recited in claim 1.

Burke et al. disclose ribozymes having a double-stranded RNA and a single-stranded loop or single-stranded RNA-protein binding site incorporated into their structure, binding of ligands (e.g., proteins) to these binding-sites may improve the activity of the ribozyme (see col. 3, lines 39-50). The site may be incorporated in a manner that does not significantly decrease the catalytic activity of the ribozyme. This site allows a protein to specifically bind to the ribozyme, and thereby potentially enhance activity and create a ribonucleoprotein that may be more efficiently targeted to a RNA substrate molecule (col. 3, lines 39-50). The term "ligand" according to Burke et al. is meant a macromolecule (e.g., peptide, protein, alkaloid, or lipid) that

Art Unit: 1635

can contact a double-stranded RNA and a single-stranded loop or single-stranded RNA with high specificity and a high affinity (col. 3, lines 52-55). In one example, Burke et al. show that the introduction of an R17 coat protein-binding site in a hairpin ribozyme structure does not interfere with the enzyme activity, but actually improves its cleavage rate by 2-fold. The R17 coat-protein (R17cp) originates from the *E. coli* R17 RNA bacteriophage and is a polypeptide that "comprises" at least about 7 to 20 or 7 to 12 amino acids (absent evidence to the contrary, this protein may function exogenously or endogenously). Burke et al. show that an increase in catalytic efficiency correlates with stabilization of the ribozyme tertiary structure. The R17 coat protein binds the modified ribozyme as efficiently as its native binding site, does not reduce catalysis, and remains associated with the ribozyme during catalysis. Therefore, a ribozyme can function efficiently in vitro as a ribonucleoprotein (col. 3, lines 56-67; and col. 4, lines 1-4). Moreover, Burke et al. state that those skilled in the art will recognize that the R17 coat protein example is non-limiting, and that other protein binding sequences can be readily provided in other locations for both single and double stranded RNA binding proteins (col. 10, lines 45-54). Additionally, the ribozymes of Burke et al. include those having nucleotides that may be modified at the sugar, base or phosphate (col. 6, lines 5-6; Figure 3).

The ribozymes of Burke et al. may be inserted into transcription units and can be incorporated into a variety of vectors for introduction into mammalian cells, including but not restricted to, plasmid DNA vectors, viral DNA vectors (such as adenovirus or adeno-associated vectors), or viral RNA vectors (such as retroviral, Semliki forest virus, sindbis virus vectors) (col. 16, lines 46-52).

Burke et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-14 and 128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1, and those claims dependent thereon, claims 2-14, recite the limitation "the peptide" in line 2 of claim 1. There is insufficient antecedent basis for this limitation in the claim. Moreover, it is unclear if "the peptide," recited in line 2 of claim 1, refers to the "polypeptide" in line 1 of claim 1.

Claims 3-4 recite the limitation "a peptide," this term is vague and indefinite since it is unclear if this term refers to "the peptide" recited in line 2 of claim 1, or if it refers to a different peptide. Claims 12-14, which depend from claim 1, also recite the limitation "the peptide," however since there is insufficient antecedent basis for this limitation in claim 1, it is unclear if this term refers to "the polypeptide" of claim 1 or the "the peptide" in line 2 of claim 1.

Claim 128 recites the limitation "the peptide" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1635

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE


SEAN MCGARRY
PRIMARY EXAMINER